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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Certifier A. Corbin

[Docket No. 00P-1439]

Iceberg Water Deviating From Identity Standard; Extension of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the extension of a temporary permit issued to Iceberg Industries Corp., to market test products designated as "Borealis Iceberg Water," a name not otherwise permissible under the U.S. standard of identity for bottled water. The extension will allow the permit holder to continue to collect data on consumer acceptance of products while the agency takes action on a petition to amend the standard of identity for bottled water, which was submitted by the permit holder.

DATES: The new expiration date of the permit will be either the effective date of a final rule amending the standard of identity for bottled water that may result from the permit holder's petition or 30 days after denial of the petition, whichever the case may be.

FOR FURTHER INFORMATION CONTACT: Loretta A. Carey, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301-436-2371.

SUPPLEMENTARY INFORMATION: In accordance with § 130.17 (21 CFR 130.17), FDA issued a temporary permit to Iceberg Industries Corp., 16 Forest Rd., suite 300, St. John's, Newfoundland, Canada, A1C 2B9, to market test products identified as "iceberg water" a name that is not permitted under the U.S. standard of identity for bottled water in § 165.110 (21 CFR 165.110) (65 FR 54283, September 7, 2000). The agency issued the permit to facilitate market testing of products whose

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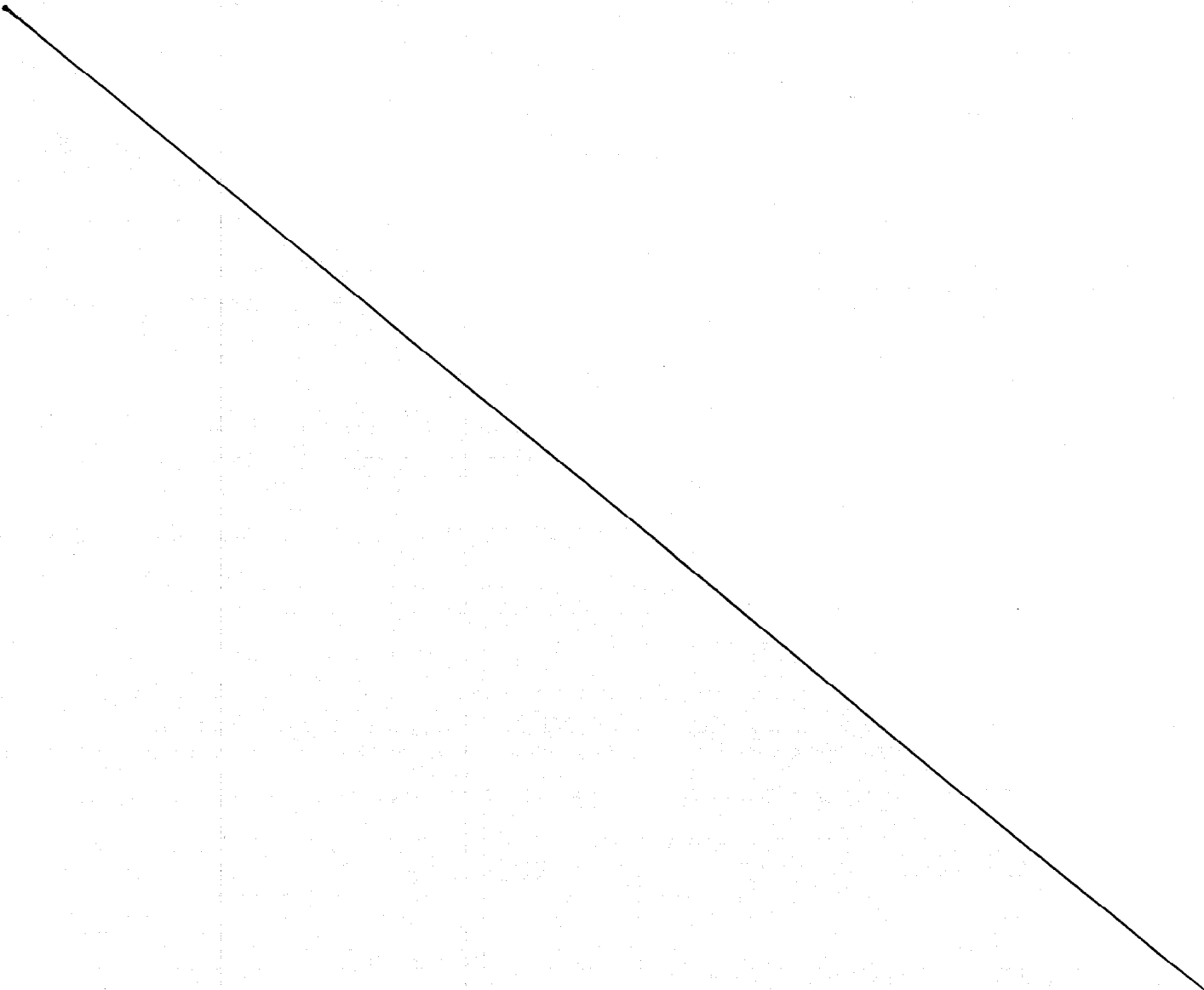
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labeling differs from the requirements of the standard of identity for bottled water issued under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). The permit covers limited interstate market testing of products that deviate from the standard for bottled water in § 165.110 in that they are identified as “iceberg water” rather than as “bottled water” or one of the other names specified in § 165.110(a)(2). The test product meets all the requirements of the standard with the exception of this deviation.

On September 28, 2001, Iceberg Industries Corp. requested that its temporary permit be extended to allow for additional time for the market testing of its products under the permit in order to gain additional information in support of its petition. The petitioner requests FDA to amend the standard of identity for bottled water to provide for a new kind of bottled water, “iceberg water,” and to require icebergs in a marine environment as its source.

The agency finds that it is in the interest of consumers to issue an extension of the time period for the market testing of products identified as iceberg water to gain information on consumer expectations and acceptance. FDA is inviting interested persons to participate in the market test under the conditions that apply to Iceberg Industries Corp. (e.g., the composition of the test product), except for the designated area of distribution. Any person who wishes to participate in the extended market test must notify, in writing, the Team Leader, Conventional Foods Team, Division of Standards and Labeling Regulations, Office of Nutritional Products, Labeling and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS-822), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. The notification must include a description of the test products to be distributed, justification for the amount requested, the area of distribution, and the labeling that will be used for the test product (i.e., a draft label for each size of container and each brand of product to be market tested). The information panel of the label must bear nutrition labeling in accordance with 21 CFR 101.9. Each of the ingredients used in the food must be declared on the label as required by the applicable sections of 21 CFR part 101.

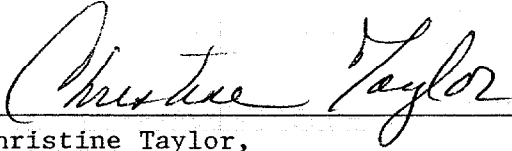
Therefore, under the provisions of § 130.17(i), FDA is extending the temporary permit granted to Iceberg Industries Corp., 16 Forest Rd., suite 300, St. John's, Newfoundland, Canada, A1C 2B9 to provide for continued market testing on an annual basis of 150,000 cases of the 24 x 350 milliliters (mL), 150,000 cases of the 12 x 1 liters (L), and another 100,000 cases of the 24 x 500 mL giving 400,000 cases in total. The total fluid weight of the test product will be 1,124,024 gallons or 4,260,000 L. The test products will bear the name "Borealis Iceberg Water." FDA is extending the expiration date of the permit so that the permit expires either on the effective date of a final rule amending the standard of identity for bottled water that may result from



the permit holder's petition or 30 days after denial of the petition, whichever the case may be.

All other conditions and terms of this permit remain the same.

Dated: 6/18/02
June 18, 2002.



Christine Taylor,
Director, Office of Nutritional Products, Labeling
and Dietary Supplements,
Center for Food Safety and Applied Nutrition.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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